	VISION(n=267)	PENTA (n=200)	TETRA (n=202)
Lesion length (mm)	10.55	12.90	10.94
Ref Vessel Diameter (mm)	2.94	2.91	2.93
GP IIb/IIIa Use %	53	44	50
Device success %	100	99	99.5
Acute Dissection %	0.8	2.5	1.0
MACE* (30 days) %	1.9	1.0	2.0
TVF ** (180 days) %	6.7	9.7	12.8
Stent Thrombosis at 30 days %	0.4	0.5	0.0
Late loss (180 days) mm	0.83	0.90	1.05
Binary restenosis (180 days) %	15.7	17.5	23.6
*MACE = death, MI, target site revasc	**TVR = death, MI, target site revasc or target vessel revasc		

1150-184 **Randomized Intravascular Ultrasound Comparison Between Patients That Underwent Amorphous Hydrogenated Silicon-Carbide Coated Stent Deployment Versus Uncoated Stents**

Luiz F. Tanajura, Alexandre A. Abizaid, Fausto Feres, Ibraim Pinto, Luiz Mattos, Rodolfo Staico, Joao de Paula, Andrea S. Abizaid, Marinella Centemero, Aurea J. Chaves, Angela Paes, Ana Seixas, Amanda Sousa, Jose Eduardo M. Sousa, Institute Dante Pazzanese of Cardiology, Sao Paulo, Brazil

Background: In-stent restenosis remains the the main limitation of percutaneous coronary intervention. Amorphous hydrogenated silicon carbide (a-SiC: H) has been shown to reduce the deposition of fibrin, platelets and leukocytes over the stent, improving hemocompatibility and biocompatibility. Thus, a-SiC:H coated stents can reduce intimal hyperplasia and restenosis. **Methods:** we conducted a prospective, randomized, open label and single center trial to compare the performance of a a-SiC:H coated stent with a bare stent in patients with stable and unstable coronary artery disease. We included 100 patients(50 patients in each group)and the primary end point was in-stent volume of intimal hyperplasia (IVHI) measured by IVUS. Because stent length was not identical we assessed absolute (per patient) and relative (divided per mm of stent length) IVHI. Secondary end points included binary restenosis rate, minimal luminal diameter, TVR and MACE at six months follow-up. Angiographic patterns of restenosis were classified according to the proposition of Mehran et al. **Results:** the two groups were similar with respect to all variables examined. Procedural success was 100%. At six months, follow-up coronary angiography was obtained in 94% of patients in both groups and IVUS was performed in 92% of both subsets. Absolute IVHI was greater in a-SiC:H patients (51.2 ± 18.8 mm^3 versus 41.9 ± 16.4 mm^3; p=0.01) but relative IVHI was similar (2.9 ± 1.0 mm^3 versus 2.5 ± 0.9 mm^3; p=0.10). Volume obstruction obtained by IVUS (36.4 ± 11.1% versus 37.9 ± 10.9%; p = 0.29) was also similar. Follow-up minimal luminal diameter (1.9 ± 0.7 versus 1.8 ± 0.6 mm; p=0.55), restenosis (19.1 % versus 17%; p=0.99), TVR (16% versus 14%; p=0.99) and MACE (20% versus 16%; p=0.79) occurred similarly. Focal and diffuse restenosis were similar. **Conclusions:** We can conclude: 1) a-SiC:H coating did not reduce IVHI, measured by IVUS; 2) follow-up minimal luminal diameter, binary restenosis, TVR and MACE were similar.

1150-185 **Experimental Evaluation of a Novel Balloon Expandable Stent and Delivery System for Treatment of Coronary Bifurcation Lesions**

Andrew J. Carter, Denise Ambrose, Lori Gibson, Lisa Welch, Leslie Coleman, Renu Virmani, Providence Heart Institute, Portland, OR, Armed Forces Institute of Pathology, Washington, DC

Experimental Evaluation of a Novel Balloon Expandable Stent and Delivery System for Treatment of Coronary Bifurcation Lesions

Andrew J. Carter, Denise Ambrose, Lisa Welch, Lori Gibson, Leslie Coleman, Renu Virmani

Providence Heart Institute, Portland OR; Armed Forces Institute of Pathology, Washington, DC

Background: Coronary bifurcation lesions present unique challenges for intracoronary stenting despite the adoption of new techniques and also have a higher probability for in-stent restenosis than *de novo* non-bifurcation lesions.

Methods: We evaluated the feasibility and biocompatibility of a novel balloon expandable stainless steel bifurcation stent with side-branch aperture support geometry mounted on a 7F compatible over-the-wire delivery system (MULTI-LINK Frontier™) with co-axial parent and side-branch "kissing' balloons, a single inflation port, and separate guide wire lumens to preserve vessel access.

Results: Twenty-five of 25 (100%) bifurcation stents were successfully implanted in the coronary arteries of 13 juvenile normolipemic swine in straight (n = 17) or bifurcation (n = 8) segments. Coronary angiography after implant and at 28-days documented side-branch patency in 8 of 8 bifurcation vessels with TIMI-3 flow. At 28-days, histology demonstrated mild strut associated inflammation for bifurcation and non-bifurcation implants while vessel injury scores tended to be greater in the bifurcation (0.20 ± 0.17) as compared to the non-bifurcation implants (0.09 ± 0.06, p = 0.04). The mean neointimal area, however, was similar for the bifurcation (2.80 ± 0.8 mm^2) and non-bifurcation (2.50 ± 0.70 mm^2) implants (p = 0.50) which resulted in an equivalent percent area stenosis for the stents implanted at a bifurcation (33.7 ± 10.7 %) or a non-bifurcation (28.3 ± 8.7 %) segment (p = 0.23).

Conclusions: The MULTI-LINK Frontier™ stent and delivery system facilitates treatment of bifurcation lesions by preserving guide wire position, side-branch access and providing stent coverage of the parent vessel and side-branch ostium. Vascular biocompatibility is acceptable in bifurcation and non-bifurcation vessels.

1150-186 **A Novel Biodegradable Coronary Polymer Stent With Drug Delivery Capacities: Paclitaxel Loading Inhibits Neointimal Hyperplasia in a Porcine Model of Coronary Restenosis**

Felix Vogt, Andreas Stein, Goesta Rettemeier, Nicole Krott, Rainer Hoffmann, Anja-Katrin Bosserhoff, Walter Michaeli, Sasan Habibi-Naini, Ruediger Blindt, University of Aachen, Aachen, Germany

Background: Due to the thrombogenic tendency and permanent implant nature of metal stents, synthetic polymers have been proposed as surrogate materials for stents and local drug delivery systems. Paclitaxel has been shown to inhibit vascular smooth muscle cell proliferation and migration.

Methods: A novel biodegradable double-helical stent was manufactured using Controlled Expansion of Saturated Polymers (CESP) for the moulding of a bioresorbable poly(D,L)-lactid acid (PDLLA). The whole blood flow Chandler loop model was used for testing in vitro hemocompatibility of the stent. In vitro drug release of loaded paclitaxel was measured using Enzyme Linked ImmunoSorbent Assay (ELISA). A modified balloon catheter for stent deployment was developed according to the mechanical stent properties. Six paclitaxel loaded (170 µg/stent) and 6 unloaded polymer stents were deployed in right coronary arteries of domestic pigs (n=12). Sacrification was performed after 3 weeks. The Cross Section Area (CSA) of the neointima was assessed by histomorphometric analysis.

Results: Sufficient in vivo hemocompatibility and mechanic stability of the stent and continuing drug release of paclitaxel loaded stents for at least one month could be demonstrated. Mean CSA of the neointima after paxlitaxel loaded stent implantation was reduced by 75% compared to non-loaded stents after 3 weeks (p=0.008).

Conclusions: These results indicate that high-molecular polylactids constitute interesting materials for polymer stents in combination with new manufacturing techniques. The novel polymer stent showed sufficient mechanic stability, and by incorporation of paclitaxel, a significant potential to reduce restenosis development after vascular intervention.

POSTER SESSION

1151 New Intravascular Approaches to Imaging

Tuesday, April 01, 2003, 9:00 a.m.-11:00 a.m.
McCormick Place, Hall A
Presentation Hour: 9:00 a.m.-10:00 a.m.

1151-173 **Relationship Between Right Ventricular Pressure Variability and Heart Failure Related Adverse Events**

Philip B. Adamson, Anthony Magalski, Robert C. Bourge, Brandon S. Sparks, Michael R. Hill, University of Oklahoma Health Sciences Center, Oklahoma City, OK, Medtronic Inc., Minneapolis, MN

Background: An investigational Implantable Hemodynamic Monitor (IHM) collects continuous, ambulatory right ventricular (RV) pressures. The objective of this analysis was to determine if RV pressure variability could be used to differentiate heart failure (HF) related adverse events.

Methods: One hundred HF subjects (NYHA class II-IV) were implanted with the IHM system. Adverse events were reported on standard case report forms. RV systolic, diastolic and estimated pulmonary artery diastolic (Epad) pressure data were continuously collected by the device and stored in 6 to 24 minute intervals. A daily median pressure and daily range (max 94^{th} percentiles - min 6^{th} percentiles) were derived from these intervals. The estimate of within day variability was calculated as the mean of the daily RV pressure ranges. The estimate of day-to-day variability was calculated as the standard deviation of the daily median RV pressures. Both estimates were calculated from data from implantation to study exit or database cutoff. HF Adverse events were related to the pressure variability estimates using Cox Proportional Hazard's regression.

Results: 82 subjects had at least one heart failure related adverse event. The time to event ranged between 0 and 13 months with a mean of two months. Of the 18 subjects without an event, follow-up ranged from 1 to 26 months with a mean of 15 months. For all RV pressures, a non-linear relationship (smoothing spline) was found between the risk of a HF related event and the mean RV pressure range (p < 0.039 for all). Relatively larger or smaller ranges (within day variability) were related to an increased risk of event. For diastolic and Epad pressures, as the standard deviation (day-to-day variability) increased, so did the risk of an event (p = 0.051, p = 0.074 respectively).

Conclusions: The variability of RV pressure within days and from day-to-day was related to HF adverse events. Subjects with lower day-to-day variability and moderate within day variability were at lower risk of HF related adverse events. These results indicate continuous, ambulatory RV pressure may be a tool that physicians can use to guide therapy to better manage patients with HF.